CLAIMS

- 1. A pharmaceutical composition comprising, in powder form: (a) at least one active hematinic species (AHS) in a therapeutically effective total amount constituting about 30% to about 95% by weight, (b) a parenterally acceptable buffering agent in an amount of about 5% to about 60% by weight, and (c) other parenterally acceptable excipient ingredients in a total amount of zero to about 10% by weight, of the composition; said composition being reconstitutable in a parenterally acceptable liquid.
- 2. The composition of claim 1 wherein the AHS comprises a complex selected from the group consisting of ferric hydroxide sucrose complex, sodium ferric gluconate complex and ferric saccharate complex.
- 3. The composition of claim 1 wherein the complex comprises sodium ferric gluconate complex.
- 4. The composition of claim 1 wherein the complex comprises ferric hydroxide sucrose complex.
- 5. The composition of claim 1 wherein the complex comprises ferric saccharate complex.
- 6. The composition of claim 1 wherein the AHS is present in an amount of about 40% to about 90% by weight of the composition.
- 7. The composition of claim 1 wherein the AHS is present in an amount of about 50% to about 80% by weight of the composition.
- 8. The composition of claim 1 wherein the buffering agent is present in an amount of about 10% to about 60% by weight of the composition.
- 9. The composition of claim 1 wherein the buffering agent is present in an amount of about 20% to about 50% by weight of the composition.
- 10. The composition of claim 1 that consists essentially of the AHS and the buffering agent.

- 11. The composition of claim 1 wherein the buffering agent is selected from the group consisting of sodium and potassium phosphates, sodium and potassium citrates, mono-, di- and triethanolamines, tromethamine and mixtures thereof.
- 12. The composition of claim 1 wherein the buffering agent is selected from the group consisting of dibasic sodium and potassium phosphates and tromethamine.
- 13. The composition of claim 1 wherein the buffering agent is dibasic sodium phosphate.
- 14. The composition of claim 1 that, upon reconstitution, has a pH of about 7 to about 9.
- 15. An injectable composition prepared by reconstituting a composition of claim 1 in a parenterally acceptable carrier or solvent.
- 16. The composition of claim 15 wherein the carrier or solvent is aqueous.
- 17. The solution of claim 16 having pH of about 7.5 to about 8.5.
- 18. The solution of claim 16 wherein the aqueous carrier or solvent contains dextrose and/or sodium chloride.
- 19. An injectable composition prepared by reconstituting a composition of claim 3 in a parenterally acceptable carrier or solvent.
- 20. An injectable composition prepared by reconstituting a composition of claim 4 wherein the parenterally acceptable liquid is a carrier or solvent.
- 21. The solution of claim 20 wherein the carrier or solvent is aqueous.
- 22. The solution of claim 21 having pH of about 7.5 to about 8.5.
- 23. The solution of claim 21 wherein the aqueous solvent contains at least one of dextrose or sodium chloride.

- 24. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 1 in a sterile condition.
- 25. The article of manufacture of claim 24 wherein the container is a pouch or vial.
- 26. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 3 in a sterile condition.
- 27. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 4 in a sterile condition.
- 28. The article of manufacture of claim 26 wherein the sodium ferric gluconate complex is present in an iron dosage amount upon reconstitution of about 5 mg to about 100 mg per mL.
- 29. The article of manufacture of claim 27 wherein the ferric hydroxide sucrose complex is present in an iron dosage amount upon reconstitution of about 5 mg to about 100 mg per mL.
- 30. The article of manufacture of claim 26 wherein the container is a pouch or multicompartment vial.
- 31. The article of manufacture of claim 27 wherein the container is a pouch or multicompartment vial.
- reconstitutable Α process for preparing a composition, the process comprising lyophilizing an aqueous composition comprising an AHS substantially free of excipients said lyophilized AHS to form a combining comprising, by weight: (a) about 30% to about 95% of said lyophilized AHS, (b) a parenterally acceptable buffering agent 5% to about 60%, and (c) other amount of about parenterally acceptable excipient ingredients in a total amount of zero to about 10%.
- 33. The process of claim 32 wherein the AHS is sodium ferric gluconate complex.

- 34. The process of claim 32 wherein the AHS is ferric hydroxide sucrose complex.
- 35. The process of claim 32 wherein the AHS is ferric saccharate complex.
- 36. A method of treating or preventing an iron deficiency disorder in a subject, the method comprising reconstituting a unit dosage amount of the composition of claim 1 to form a parenterally administratable composition, and administering the composition to the subject.
- 37. The method of claim 36 wherein the parenteral administration is by intradermal, subcutaneous, intramuscular, intravenous, intramedullary, intra-articular, intrasynovial, intraspinal, intrathecal or intracardiac injection or infusion.
- 38. The method of claim 36 wherein the parenteral administration is by intravenous injection or infusion.
- 39. The method of claim 38 wherein the composition is injected intravenously as a bolus.
- method of treating or preventing an deficiency disorder in a subject, the method comprising reconstituting a unit dosage amount of a composition of claim 5 in а physiologically acceptable amount parenterally acceptable solvent liquid to form an injectable solution, and administering the solution parenterally to the subject.
- 41. The method of claim 40 wherein the parenteral administration is by intradermal, subcutaneous, intramuscular, intravenous, intramedullary, intra-articular, intrasynovial, intraspinal, intrathecal or intracardiac injection or infusion.
- 42. The method of claim 40 wherein the parenteral administration is by intravenous injection or infusion.
- 43. The method of claim 42 wherein the composition is injected intravenously as a bolus.